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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,837

04/17/2006

Tomoko Hongo

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466 7590 06/26/2009

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EXAMINER

WANG, CHUN CHENG

ART UNIT

PAPER NUMBER

1796

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06/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,837	Applicant(s) HONGO ET AL.	
	Examiner Chun-Cheng Wang	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36, 38 and 54-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 38 and 54-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the Amendment filed on 04/27/2009. Claims 37 and 39-53 have been cancelled. Claims 34-36, 38 and 54-64 are now pending.
2. The objections and rejections not addressed below are deemed withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this section can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

4. Claims 34-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Katsuhiro et al. (JP 2002-180110).

The rejections stand as per the reasons set forth in paragraph 8 of the previous Office Action, incorporated herein by reference.

The metal colloid solution is capable of performing the intended use, in an integrity test for a virus removal membrane.

Claim Rejections - 35 USC § 102/103

5. Claims 34, 36 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Golden et al. (DE 19803891).

The colloid solution has intended use for integrity test for a virus removal membrane. Gordon et al. disclose aqueous precious metal colloids in the form of a sol with metal particles of 0.5-100 nm. The colloids can be obtained by reduction of a precious metal salt or complex dissolved in water by using an organic reducing agent in the presence of a water soluble polymer and optionally in the presence of multivalent anions (Abstract). Aqueous solution of H₂PtCl₆ and water was mixed. In a second vessel polyvinylpyrrolidone and sodium citrate dihydrate in water

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was dissolved. The two solutions subsequently mixed and bottom reflux up to the boiling point (page 4, Example 1.).

Gordon et al. is silent on the stability of the colloid solution. However, in view of the substantial identical colloid solution composition, the composition and adduct would possess the claimed properties. Since PTO does not have proper means to conduct experiments, the burden of proofs is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald* 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

6. Claims 54 and 56-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer et al. ("Filtration in the Pharmaceutical Industry", Marcel Dekker, New York, 1998, page 548-559 and 636-637) in view of Katsuhiko et al. (JP 2002-180110).

The rejections stand as per the reasons set forth in paragraph 12 of the previous Office Action, incorporated herein by reference.

The integrity test method is intended to use for a virus removal membrane for confirming the removability performance of the virus removal membrane.

Although Meltzer et al. is silent on washing the membrane after virus removal. It is obvious to clean/disinfect the membrane after used for virus removal before any further testing (motivation).

Meltzer et al. disclose protein adsorption test on modified polyethersulfone and modified polyvinylidene fluoride (PVDF) (page 554, line 12) membranes for filtration. Both modified polyethersulfone and modified PVDF show extremely low protein adsorption (page 554, lines 16-17). The modified PVDF is hydrophilic (page 551, lines 20-21).

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7. Claims 55 and 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al. ("Scrapie Removal using Planova Removal Filters", Biological (2001) 29, page 17-25) in view of Naoki et al. (JP 2002-060805).

The rejections stand as per the reasons set forth in paragraph 13 of the previous Office Action, incorporated herein by reference.

8. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer et al. ("Filtration in the Pharmaceutical Industry", Marcel Dekker, New York, 1998, page 548-559 and 636-637) in view of Katsuhiko et al. (JP 2002-180110) as applied to claims 54 and 56-61 above, and further in view of Causserand et al. ("Study of the effects of defects in ultrafiltration membranes on the water flux and the molecular weight cut-off", Desalination, 10 September 2002, 149, Issue 1-3, pages 485-491).

The disclosure of Meltzer et al. and Katsuhiko et al. is adequately set forth in paragraph 5 and is incorporated herein by reference.

Meltzer et al. and Katsuhiko et al. are silent on using alkaline solution to wash the membrane.

Causserand et al. disclose dextran and protein ultrafiltration experiment set-up by using a molecular weight cut-off membrane to evaluate how defects in a membrane surface can affect the molecular weight cut-off (MWCO) and the membrane permeability. The membrane was pre-washed and cleaned with alkaline solution at pH 12.3 without neutralization (page 487, 2.2. *Ultrafiltration set-up procedure*).

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Washing and cleaning the membrane allowing one to evaluate how defects in a membrane surface can affect the molecular weight cut-off and the membrane permeability. In light of such benefit, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to wash the membrane with alkaline solution without neutralization and would have reasonable expectation of success.

Response to Arguments

9. Applicant's arguments filed 04/27/2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102:

10. Applicants alleged: Katsuhiko et al. required the combination of two metal salts.

Response: The colloid solution of Katsuhiko et al. meet the "A colloid solution ... comprising: (1) metal particles or metal compound particles" limitation.

11. Applicants alleged: Katsuhiko et al. failed to combine surfactant agent including polyvinylpyrrolidone and surfactant agents and/or chelating agents.

Response: Attention is drawn to Example 4 [0045]. Trisodium citrate dehydrate (chelating agent) and polyvinylpyrrolidone are mixed together to prepare the colloid solution.

Claim Rejections - 35 USC § 103:

12. Regarding references Katsuhiko et al. and Meltzer et al.: In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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13. Applicants alleged: Meltzer et al. does not teach or suggest using thermoplastic synthetic polymeric membrane.

Response: Meltzer et al. disclose using hydrolyzed thermoplastic synthetic polymeric membrane (see paragraphs 11-12 of the previous Office Action). The modified PVDF is hydrophilic (page 551, lines 20-21).

14. Applicants alleged: Noaki et al. required the combination of two or more metals.

Response: The colloid solution of Katsuhiko et al. meet the "A colloid solution ... comprising: (1) metal particles or metal compound particles" limitation.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 03/13/2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun-Cheng Wang whose telephone number is (571)270-5459.

The examiner can normally be reached on Monday to Friday w/alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/
Primary Examiner, Art Unit 1796

/Chun-Cheng Wang/
Examiner, Art Unit 1796

/CCW/